UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE REMICADE ANTITRUST LITIGATION This document relates to: Indirect Purchaser Actions Direct Purchaser Actions	: : : : :	CIVIL ACTION No. 17-cv-04326 (consolidated) No. 18-cv-00303 (consolidated)

PFIZER INC., Plaintiff, v. JOHNSON & JOHNSON and JANSSEN BIOTECH, INC., Defendants.	: : : : : :	CIVIL ACTION No. 17-cv-04180

WALGREEN CO. and THE KROGER CO., Plaintiffs, v. JOHNSON & JOHNSON and JANSSEN BIOTECH, INC., Defendants.	: : : : : :	CIVIL ACTION No. 18-cv-02357

JOINT CASE MANAGEMENT STATUS REPORT

Plaintiffs Pfizer Inc. ("Pfizer"), direct purchaser class plaintiffs ("DPPs"),[1] indirect purchaser class plaintiffs ("IPPs") (the DPPs and IPPs together, the "Class Plaintiffs"), and retailer plaintiffs Walgreen Co. and the Kroger Co. ("Retailers") (collectively, "Plaintiffs") and defendants Johnson & Johnson and Janssen Biotech, Inc. (collectively, "Defendants" or "J&J"), respectfully submit this joint case management report of their Rule 26(f) conference in advance

[1] J&J and the DPPs agree that the DPPs may participate in this report and the upcoming status conference with the understanding that: (1) DPPs will not argue that their participation in discovery constitutes a waiver of arbitration by Defendants; and (2) neither DPPs nor Defendants waive or are prejudiced in their ability to make any arguments made in the motion to compel arbitration briefing as a result of the preceding agreement or DPPs' participation in discovery.

of the Rule 16 conference in *Pfizer Inc. v. Johnson & Johnson*, No. 17-4180 (the "*Pfizer* Action") scheduled for September 27, 2018.[2]

On December 19, 2017, Pfizer and J&J submitted a joint Rule 26(f) report and a proposed pretrial schedule.[3] On February 20, 2018, the IPPs and J&J submitted a joint Rule 26(f) report and a proposed pretrial schedule.[4] The Court then stayed discovery in the *Pfizer* Action on February 26, 2018 pending its ruling on Defendants' motion to dismiss the Pfizer complaint.[5] By operation of agreements among the parties and applicable court orders, the stay entered in the *Pfizer* action effectively also stayed the DPP, IPP, and Retailer actions.. On August 10, 2018, the Court denied J&J's motion to dismiss Pfizer's complaint and lifted the stay of discovery in the *Pfizer* Action, the effect of which lifted the stay as to all the other related pending actions.[6] In advance of the Rule 16 conference, the parties submit this updated, consolidated joint case management status report, which supersedes all prior reports, and attach a chart showing each side's proposed pretrial schedule.

I. Fully Briefed Pending Motions

A. In the DPP Action, 18-cv-303: *Defendants' Motion to Compel Individual Arbitration and Stay Proceedings*, filed April 9, 2018.

1. Applicable 18-cv-303 docket numbers: 29 (opening); 40-41 (opposition); 46, 48 (reply); and 53, 55-56 (sur-reply).

B. In the DPP and IPP Actions, 18-cv-303 and 17-cv-4326: *Defendants' Motions (1) to Dismiss the Indirect Purchasers' Consolidated Amended Complaint and (2) to*

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[2] ECF No. 67. "ECF" references are to the *Pfizer* Action, unless otherwise noted.

[3] ECF No. 38.

[4] *See* ECF No. 52, *In re Remicade Antitrust Litig.*, No. 17-04326 (E.D. Pa.).

[5] ECF No. 50.

[6] *Compare* ECF 59, *with* Feb. 27, 2018 Memorandum entered in 17-cv-4180 (ECF 49), at 1 n.1 (as corrected by Mar. 22, 2018 Order (ECF 51)), *and* Jun. 20, 2018 Order entered in 18-cv-2357 (ECF 10).

Dismiss the Amended Direct Purchaser Class Action Complaint if Motion to Compel Individual Arbitration and Stay Proceedings Is Denied, filed April 9, 2018.

1. Applicable 18-cv-303 docket numbers: 31 (opening); 39 (opposition); 44 (notice of supplemental authority); and 47 (reply).

2. Applicable 17-cv-4326 docket numbers: 67 (opening); 73 (opposition); 74 (notice of supplemental authority); and 75 (reply).

II. Summary of Case Management Disputes

While, as discussed below in detail, the parties have reached agreement on a number of issues, for the convenience of the Court the main areas of dispute remaining are:

1. **Sequencing of Class Certification and Expert Discovery.** Plaintiffs' position (and particularly the Class Plaintiffs) is that class expert discovery, merits expert discovery, and briefing on the IPP's and DPP's class certification motions should not be separately phased with additional time added to the schedule because the class and merits issues are likely to be heavily intermeshed and accordingly can be more efficiently addressed at once by the simultaneous submission of both class and merit expert reports. Pfizer's and Retailers' positions are that merits expert discovery and dispositive motions in their cases should not be delayed due to class certification motions. J&J's position is that the parties should first proceed with class expert discovery and briefing on the IPP's and DPP's class certification motions, and then proceed to merits expert discovery thereafter. Class and merits issues are unlikely to be linked to such an extent that substantial efficiencies will be realized by simultaneous class and merits expert discovery. J&J's proposed schedule will also allow for all parties to incorporate the impact of the Court's ruling on class certification, which may significantly alter the scope of the case and,

with respect to the IPPs and DPPs, may effectively remove the need for further expert discovery. Separating class and merits expert discovery is most likely to avoid unnecessary work on expert submissions that are unnecessary or may need to be revised in light of the Court's rulings on class certification.

2. **Sur-replies.** Class Plaintiffs' position is that sur-replies for class certification are the exception, not the rule, and should therefore not be provided for in the schedule as a matter of course. J&J's position is that class sur-replies may be necessary if Class Plaintiffs' reply briefs include new argument. As provided in J&J's proposed schedule, J&J will only seek leave to file a sur-reply should new issues be raised by Class Plaintiffs' reply brief.

3. **Timing of Trial Following Summary Judgment.** Plaintiffs' position is that pretrial preparation should not be on hold pending a ruling on motions for summary judgment. The sudden halting of all final pre-trial preparations, when the parties have just sifted through and assessed the pertinent evidence for purposes of the summary judgment submissions, creates an unnecessary delay. To the extent motions for summary judgment are denied, the parties will be ready for trial, and if the scope of any issues are narrowed, the parties will more easily be able to amend their pretrial submissions than start from scratch after a period of inactivity. J&J's proposed schedule provides for pre-trial submissions beginning one month after the Court's ruling on any motions for summary judgment. J&J submits this process will be more efficient, as the Court's rulings on summary judgment will affect preparations for trial. To the extent motions for summary judgment are granted in their entirety, no pre-trial submissions will be necessary. And to the extent the motions are granted in part, requiring pre-trial submissions only after a ruling will prevent the parties from needing to duplicate work by amending their pretrial submissions.

The parties' respective positions are explained in detail below.

III. Summary of Claims and Defenses

A. Pfizer's, DPPs', and Retailers' Summary of Their Claims:

In 2016, Pfizer launched Inflectra (infliximab), an FDA-approved "biosimilar" drug, which is designed and approved as a substitute for J&J's long-entrenched Remicade (infliximab). J&J, however, has used its monopoly position and exclusionary tactics to unfairly stifle competition in the relevant market. This violates the antitrust laws and also thwarts Congress's purpose in enacting the Biologics Price Competition and Innovation Act, which is intended to foster meaningful price competition for long-entrenched branded biologic products like Remicade. J&J's exclusionary tactics with health insurers and providers, and other actions, have led to the near total foreclosure of Inflectra and other infliximab biosimilars from patients across the country. This conduct has harmed the competitive process and deprived the marketplace of the principal benefits of competition—more choices and lower prices—causing harm to Pfizer and substantial overcharges to the DPPs, IPPs, and Retailers. Pfizer asserts four causes of action: (1) Monopolization under Section 2 of the Sherman Act, (2) Attempted Monopolization under Section 2 of the Sherman Act, (3) Sale on Condition to Exclude Inflectra and Other Infliximab Biosimilars under Section 3 of the Clayton Act, and (4) Agreements in Restraint of Trade under Section 1 of the Sherman Act. Pfizer is seeking trebled damages, costs, including its reasonable attorneys' fees and court costs, permanent injunctive relief and other relief.

The DPPs assert two causes of action: (1) Monopolization under Section 2 of the Sherman Act, and (2) Contracts in Restraint of Trade under Section 1 of the Sherman Act. The DPPs are seeking damages of three times overcharges, costs, including attorneys' fees, and other relief. Defendants' motion to dismiss those claims are without merit as, among other reasons,

DPPs have alleged antitrust injury in the form of infliximab overcharges. (ECF 39, *In re Remicade Antitrust Litig.*, Case No. 2:18-cv-00303 (E.D. Pa.)). Nor are DPPs antitrust claims subject to arbitration. *Id.* at ECF Nos. 40-41, 53, and 55-56.

The Retailers assert three causes of action: (1) Monopolization under section 2 of the Sherman Act; (2) Attempted Monopolization under section 2 of the Sherman Act; and (3) Conspiracy in Restraint of Trade under section 1 of the Sherman Act. Retailers are seeking damages of three times overcharges, costs, including attorneys' fees, permanent injunctive relief and other relief.

B. Indirect Purchaser Plaintiffs' Summary of Their Claims:

The Indirect Purchaser Plaintiffs allege that in an effort to maintain and extend its monopoly for Remicade, J&J worked to suppress competition and raise prices to purchasers of the biologic by imposing a web of exclusionary contracts on both health insurers and healthcare providers. In addition to the exclusionary contracts, the IPPs also allege J&J engaged in other anticompetitive acts, including bundling other J&J products with Remicade, implementing coercive rebate policies and filing sham patent litigation. Plaintiffs National Employees Health Plan, Local 295 IBT Employer Group Welfare Fund and the Welfare Fund of Plumbers Local Union No. 200 bring claims under Federal and state antitrust law as well as under various state consumer protection statutes, for damages and injunctive relief. Indirect Purchaser Plaintiffs also bring claims alleging Walker Process Fraud related to J&J's wrongfully asserted patent claims against potential competitors.

C. J&J's Summary of Its Defenses:

J&J denies Plaintiffs' allegations that it has engaged in anticompetitive conduct in violation of the Sherman or Clayton Acts. To the extent Pfizer's Inflectra has failed to meet

Pfizer's expectations in the market, that is due to Pfizer's failure to compete effectively. In addition, (1) Remicade has a long and successful clinical history with which physicians and payors are familiar, whereas biosimilars like Inflectra do not; (2) the FDA has not deemed Inflectra to be interchangeable with Remicade; (3) Remicade is cost-effective and widely covered due in part to the rebates and discounts that Janssen provides to payors and providers; (4) the FDA has approved several drugs for the treatment of the same indications as Inflectra, and Inflectra must compete against all of these drugs, including Remicade, to succeed; and (5) the entire concept of a "biosimilar" is new, with the first biosimilar approval in 2015, so physicians are not familiar with them.

J&J's defenses in the *Pfizer* Action include: (1) Pfizer has not suffered an injury cognizable under the antitrust laws; (2) Pfizer has not shown harm to competition as J&J's rebates and discounts on Remicade are an integral part of the competitive process; (3) Pfizer has not made substantial efforts to compete with J&J either on price or by offering its own competitive bundle; (4) Pfizer has not properly defined the market; (5) J&J's contracts are procompetitive, and do not cause harm to competition or to Pfizer; and (6) the market for drugs to treat the relevant indications is competitive.

With respect to the DPPs, plaintiff Rochester Drug Cooperative Inc.'s ("Rochester") complaint is subject to mandatory arbitration, and Janssen has filed a motion to compel arbitration of Rochester's claims on an individual basis. *See* ECF 29, *In re Remicade Antitrust Litig.*, Case No. 2:18-cv-00303 (E.D. Pa.). To the extent Rochester is not compelled to arbitrate, J&J's defenses to the DPPs' claims, as set forth in its motion to dismiss, include that the DPPs have failed to plead sufficient facts to establish a cognizable antitrust injury. And should the case proceed beyond the motion to dismiss, J&J will also raise additional defenses, including those

relating to the definition of the market, the procompetitive justifications for its contracts, the lack of harm to competition or to the DPPs, and the competitive nature of the market for drugs to treat the relevant indications.

With respect to the IPPs, Janssen's defenses, as set forth in its motion to dismiss, include that the IPPs have failed to plead sufficient facts to establish a cognizable antitrust injury (and in fact, according to their allegations, are the beneficiaries of the very policies they decry in their complaint), have failed to plead facts sufficient to sustain their "sham" litigation and *Walker Process* claims, and have failed to plausibly plead elements of their state law claims. Should the case proceed beyond the motion to dismiss, J&J will raise additional defenses, including those relating to the definition of the market, the procompetitive justifications for its contracts, the lack of harm to competition or to the IPPs, and the competitive nature of the market for drugs to treat the relevant indications.

Finally, with respect to the Retailers, Janssen has similar arguments to those included in its motion to dismiss the DPP's and IPP's complaint, as well as arguments specific to the Retailers. J&J intends to submit a motion to dismiss the Retailers' complaint on September 28, 2018.

IV. Case Management Proposals

A. Initial Disclosures (Fed. R. Civ. P. 26(f)(3)(A)):

The parties agree that initial disclosures should be served on October 11, 2018, which is 14 days after the Rule 16 case management conference on September 27.

B. Proposed Discovery Schedule (Fed. R. Civ. P. 26(f)(3)(B)):

1. Plaintiffs' Position

The Court has lifted the stay of discovery in all actions, and thus discovery has already commenced. On September 7, 2018, Plaintiffs served a first set of joint requests on J&J for the production of documents. The parties have agreed to sixteen months of fact discovery, starting from the Court's September 27, 2018 conference. Plaintiffs' propose approximately four months of expert discovery following the close of fact discovery. Plaintiffs also propose to conduct class-related briefing concurrently so that all class-related submissions, including any related *Daubert* challenges, are submitted before the end of expert discovery and with minimal disruption to the advancement of the non-class cases. Plaintiffs' proposed schedule is set forth in the first and second columns of Exhibit A attached hereto. J&J's proposed schedule set forth the third and fourth columns of Exhibit A, provides for inefficient and lengthy staging that, at minimum, sees this case entering the Court's trial pool over a year later than under Plaintiffs' proposed schedule (likely even more because J&J proposes staying pretrial disclosures pending a ruling on summary judgment).

2. J&J's Position

J&J served its first set of document requests on Pfizer on September 13, 2018.[7] J&J's proposed schedule provides for class certification expert discovery and briefing to be completed before the parties move into merits expert disclosures. J&J proposes that plaintiffs' merits reports due four months after the completion of class certification submissions, which will provide an opportunity for the parties to account for the Court's rulings. J&J recognizes that this will require a pause in proceedings specific to the *Pfizer* Action, but submits that a short delay is

[7] J&J anticipates serving document requests on the IPPs and Retailers in the near future. J&J anticipates serving documents requests on the DPPs if its motion to compel arbitration of Rochester's individual claims is denied.

required to allow for efficient coordination of the cases. J&J's proposed schedule then provides for merits expert discovery and pretrial motions.

C. Subjects on Which Discovery May Be Needed (Fed. R. Civ. P. 26(f)(3)(B)):

1. Plaintiffs' Position

Plaintiffs believe that all parties are entitled to discovery to the fullest extent permitted by the applicable Rules. Without limitation, Plaintiffs anticipate the need for discovery from J&J and third parties – including but not limited to manufacturers of infliximab, insurers, GPOs, hospitals, and clinics – regarding a number of topics, including (1) J&J's contracts with insurers, providers, and other third parties for Remicade, (2) negotiations between J&J and third parties regarding contracting for Remicade, (3) J&J's contracting strategies for Remicade with respect to insurers, providers, and other third parties, (4) J&J's strategies for responding to the launch of biosimilars to Remicade, including the launch of Inflectra, (5) J&J's pricing, marketing, and sales strategies for Remicade, (6) transactional sales, rebate, and discount data for Remicade and products bundled with Remicade, (7) forecasts and budgets for Remicade, (8) profit and loss statements and cost data for Remicade, (9) evaluations and analyses of competing products, (10) product market evaluations and market share analyses and forecasts, (11) communications between J&J and third parties regarding sales, marketing, and pricing for Remicade, (12) communications between J&J and third parties regarding insurance coverage and reimbursement for Remicade and for biosimilars, (13) actions taken by Defendants related to competing patents,[8] (14) evaluations and analysis of insurance coverage for Remicade and biosimilars, including Inflectra, and (15) the market foreclosure impact of the various components of J&J's anticompetitive scheme.

[8] Such discovery is relevant to claims asserted in the IPP action.

Plaintiffs are coordinating discovery and will endeavor to continue to do so in order to, for example, avoid duplicative depositions

2. IPPs' Position

In addition to the subjects listed above, the IPPs anticipate the need for discovery from J&J and third parties regarding actions taken by Defendants related to competing patents.

3. J&J's Position

J&J submits that any discovery should be coordinated between each of the cases. As to the *Pfizer* Action, likely subjects of discovery will include (1) J&J's contracting with payors and providers relating to Remicade; (2) Pfizer's contracting with payors and providers relating to Inflectra; (3) Pfizer's attempts to compete with J&J in relation to Inflectra and its decisions with regard to market prices, rebates and discounts; (4) financial and sales data relating to sales of both Remicade and Inflectra; and (5) discovery relevant to competing products with regard to the appropriate market definition. J&J anticipates that these issues will require discovery from the parties and from certain third parties. As to the DPP, IPP, and Retailer cases, to the extent those cases survive J&J's pending motion to compel arbitration of Rochester's individual claims and the pending and anticipated motions to dismiss, J&J anticipates that discovery will be required on similar subjects, as well as discovery on the specific antitrust injuries those plaintiffs claim to have suffered.

D. Discovery Phasing (Fed. R. Civ. P. 26(f)(3)(B)):

1. Plaintiffs' Position

The parties agree that fact and expert discovery should proceed sequentially with DPP and IPP class certification briefing occurring simultaneously with the exchange of expert reports regarding class certification. As indicated in Plaintiffs' proposed schedule in Exhibit A,

Plaintiffs' position is that Plaintiffs' expert reports for both class and merits issues would be served just after the close of fact discovery, and any remaining expert discovery, including J&J's expert reports, Plaintiffs' rebuttal reports, and expert depositions, as well as class certification briefing, would proceed for a total of about four months. Plaintiffs proposal is aimed at efficiency—one round of expert reports and depositions—and ensures that non-class plaintiffs (Pfizer and the Retailer Plaintiffs) need not sit on the sideline for almost a year while class issues are addressed. The efficiency gains from Plaintiffs' proposed schedule are particularly acute here where the class and merits issues in this case are heavily intermeshed and expert merits discovery will proceed regardless of the outcome of class certification[9] both because the class plaintiffs will remain parties and because Pfizer and the Retailer Plaintiffs are proceeding with non-class cases.

2. J&J's Position

The parties agree that fact and expert discovery should proceed sequentially. J&J submits that having class and merits expert discovery proceed in parallel would be inefficient, as the Court's ruling on class certification is likely to have a significant impact on the scope of the class litigation, including any merits expert testimony. Sequential class and merits expert discovery as set forth in Defendants' proposal at Exhibit A—with merits discovery proceeding after class certification—will increase the chances that the parties can avoid unnecessary burden and expense either through unnecessary expert testimony or through having to submit revised expert reports in light of any rulings by the Court.

E. Protocol for Electronically Stored Information (Fed. R. Civ. P. 26(f)(3)(C)):

The parties are meeting and conferring on a protocol for production of electronically

[9] Plaintiffs do not concede that Defendants will have any basis for opposing class certification.

stored information.

F. Issues about Confidentiality (Fed. R. Civ. P. 26(f)(3)(C)):

The parties are meeting and conferring on a proposed protective order limiting the disclosure of competitively sensitive information produced during discovery. The parties are likewise meeting and conferring on a stipulation and proposed order regarding the non-disclosure of certain information concerning expert witnesses.

G. Issues about Claims of Privilege or Protection (Fed. R. Civ. P. 26(f)(3)(D)):

The parties are meeting and conferring on a procedure for identifying all documents that are withheld (or redacted) on privilege or work product grounds.

H. Changes to Limitations on Discovery (Fed. R. Civ. P. 26(f)(3)(E)):

The parties do not propose any changes to the limitations on discovery imposed by the applicable Rules other than as listed below. Notwithstanding the proposed limits below, the parties reserve their rights to seek leave from the Court to increase the number of depositions to be taken.

1. Number of Party Depositions

The parties contemplate substantial deposition discovery and have accordingly agreed on to 52 party depositions as follows:

a. J&J is subject to a total of 20 party depositions. Plaintiffs will coordinate in the taking of those depositions.

b. Pfizer is subject to a total of 20 party depositions by J&J.

c. Each of the Class Plaintiffs and Retailers is subject to 2 party depositions by J&J.

Individuals and entities affiliated with the Parties, including current and former employees, shall count toward the party deposition limits. To the extent additional depositions

are required, the parties have reserved their rights to approach the Court at a later time, at which point the Court can consider a request for additional depositions against a record of existing and proposed additional discovery.

2. Rule 30(b)(6) Depositions

The parties have reached agreement on a procedure on how to count Rule 30(b)(6) depositions for purposes of the overall limits. Any Rule 30(b)(6) deposition of a named party counts as 1 deposition no matter the number of witnesses designated to testify, unless the deposition exceeds 7 hours. In the event that a Rule 30(b)(6) deposition exceeds 7 hours, the additional hours shall count as an additional deposition or the pro rata portion of an additional deposition (*e.g.*, if a Rule 30(b)(6) deposition lasts 14 hours, it shall count as 2 depositions out of the total party depositions allocated per side; if a Rule 30(b)(6) deposition lasts 10.5 hours, it shall count as 1½ depositions out of the total party depositions allocated per side). Subject to the per-side deposition cap, the parties are not precluded from seeking the deposition of a Rule 30(b)(6) designee in their individual capacity, which will count as an additional deposition.

3. Third-Party Depositions

The parties agree that a substantial amount of third-party depositions may be necessary in this case, and accordingly have agreed that each side (*i.e.*, all Plaintiffs constituting one side and J&J constituting the other side) may take up to 45 third-party depositions. The parties also agree that third-party depositions will not count toward the per-side deposition cap for party depositions, but should instead be subject to a separate limit. The parties agree on a protocol for dividing time at third party depositions. If only Plaintiff(s) or only J&J has noticed the third party's deposition, the noticing party will be allowed up to six hours of examination, allowing the other side up to one hour of examination. In the event Plaintiff(s) and J&J notice the same

deposition, Plaintiff(s) and J&J will each be allocated three-and-a-half hours of examination time. If one side does not use its full allotted time for all examinations of the witness (including direct and re-direct), the other side may use any remaining time for their examination. The parties agree that Plaintiffs collectively count as one side for purposes of these allocations, Plaintiffs agree to share their examination time, and all parties reserve the right to request permission for additional examination time and to exceed the third party deposition limit if they reasonably and in good faith believe such additional depositions are necessary.

4. Coordination of Discovery Among Plaintiffs

The parties in all of the above-captioned actions agree to work together, to the extent possible, to avoid duplicative discovery or undue burden, including scheduling depositions to avoid the need to depose an individual more than once.

V. Possibility of Prompt Settlement or Resolution

The parties have conferred and do not anticipate being able to promptly resolve their differences.

Dated: September 25, 2018

Respectfully submitted,

/s Adeel Mangi

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on September 25, 2018, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses on the attached Electronic Mail Notice List, and I hereby certify that I caused the mailing of the foregoing via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

s/ Alexandra S. Bernay
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Mailing Information for a Case 2:17-cv-04326-JCJ NATIONAL EMPLOYEES HEALTH PLAN v. JOHNSON & JOHNSON et al

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